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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir/Madam:

We are pleased to submit the attached ISPE GAMP response to the FDA Part 11 revisions. Our response includes a general comment letter which refers to two presentations (attached) which were due to be delivered at the cancelled public meeting. We will follow up this Email with a hard copy submission via next day courier.

Thank you for making our response part of the record. If you have any questions please contact me at (813) 960-2105.

Sincerely,

Robert P. Best
President/CEO

RPB/dwm

Attachments